

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/390,851 09/07/99 PEDERSEN

H 5655.204-US

EXAMINER

HM12/0719

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE
SUITE 6400
NEW YORK NY 10174-6401

PRASTHOFFER, T

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

07/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

file copy

Office Action Summary
Substantive Restriction

Application No.

09/390,851

Applicant(s)

PEDERSEN ET AL.

Examiner

Thomas W Prasthofer

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Detailed Action
(Substitute Restriction/Election)

Change of Examiner

The examiner of this application has changed from Barba Koroma, Ph.D. to Thomas Prasthofer, Ph.D.

Status of the Application

Receipt is acknowledged of a response to a restriction and election of species requirement on June 11, 2001 (Paper No. 13).

Status of the Claims

Claims 1-27 are pending in the present application and are subject to restriction and election of species requirements.

Reasons for Substitute Restriction/Election

1. The examiner has discovered a number of errors in the previous restriction requirement (Paper No. 11, mailed March 28, 2001) that necessitate a new restriction requirement. The examiner considers the following to be errors in the March 28, 2001 restriction requirement:

1. Groups II (claims 8-11), III (claims 12-15), and IV (claims 16 and 17) were reported as being drawn to a libraries but the claims clearly recite a methods, not libraries.

2. Group IX was separated from Group I despite there being no differences in the method steps between the claims other than the production of the selected catalyst.

Because of the identified errors in the March 28 restriction requirement, a new restriction/election requirement is necessary. The examiner regrets any inconvenience to applicant as a consequence of the aforementioned errors.

Restriction/Election

2. The examiner notes that it is not possible to search claim 1. The terms “catalyst molecules,” “individual units,” and “substrate,” for example lack any structure that can be used as a basis for search. Similarly, terms such as “in vitro selection,” catalytic activity,” and “entity comprising information” do not provide enough detail for a search of the prior art. For these reasons, applicant is required to elect a genus of catalyst and also distinct species for a number of other parameters.

3. Applicant is required to elect a genus of catalyst molecules selected from the following:

- I. **Nucleic acid** catalyst molecules, of a catalyst molecule of interest, classified in class 536, subclass 22.1.
- II. **Enzyme (or protein or peptide)** catalyst molecules, of a catalyst molecule of interest, classified in class 435, subclass 183.
- III. **Small organic** catalyst molecules, of a catalyst molecule of interest, classified in numerous classes and subclass, depending on the structures of the catalysts.
- IV. **Inorganic** catalyst molecules, of a catalyst molecule of interest, classified in numerous classes and subclass, depending on the type of inorganic catalysts.

Election of Species

4. This application contains claims directed to patentably distinct species of the claimed invention. Applicant is required to elect a distinct species within each of the following categories: (a total of nine species to be elected)

- A. catalytic activity of interest (i.e. to catalyze a particular reaction or class of reactions),
- B. species of individual units - Applicant must provide structural components that are common to all structural units, structural components that vary, whether or not individual units are biologically amplifiable, AND, if they are biologically amplifiable, a species of biologically amplifiable unit (i.e. phage, plasmid, virus, bacterium, etc.),
- C. substrate (a specific molecule or structurally related molecules are being used),
- D. entity comprising information (what is the entity and what information does it provide),
- E. species of selecting in claim 1 (ii) (i.e. method of selection),
- F. species of flexible linker in claim 4 (i.e. structure of the linker),
- G. species of carrier system in claim 5 (what is the carrier system),
- H. species of affinity tag in claim 19, AND
- I. species of specific immobilization in claim 22 (i.e. to an affinity column, a bead, a microchip, etc.)

5. The species are distinct, each from the other, because they have different chemical, physical, biological, and catalytic properties or they are different methods requiring different method steps, reagents, starting materials, and reaction conditions and/or produce different results. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas Prasthofer** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Thomas Prasthofer, Ph.D.

July 17, 2001

BENNETT CELSA
PRIMARY EXAMINER

